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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,553	02/08/2006	Silke Gruenke	MERCK-3122	9242
<div>23599 7590 09/20/2007</div> <div>MILLEN, WHITE, ZELANO & BRANIGAN, P.C.</div> <div>2200 CLARENDON BLVD.</div> <div>SUITE 1400</div> <div>ARLINGTON, VA 22201</div>				
			<div>EXAMINER</div> <div>WALLENHORST, MAUREEN</div>	
			<div>ART UNIT</div> <div>1743</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE</div> <div>09/20/2007</div>	<div>DELIVERY MODE</div> <div>PAPER</div>

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/567,553

Applicant(s)

GRUENKE ET AL.

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/8/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

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1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.
2. The abstract of the disclosure is objected to because the abstract from the corresponding PCT application should be placed onto a separate sheet. Correction is required. See MPEP § 608.01(b).
3. Claims 1-3 provide for the use of a mixture consisting of a stable water-containing compound and a stable water-free compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

4. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 are indefinite for the reasons given above. In addition, in claim 2, the phrase "the oven technique" lacks antecedent basis. In claim 3, the phrase "the Karl Fischer method" lacks antecedent basis.

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On line 3 of claim 4, the phrase “the constituents” lacks antecedent basis. See this same problem on lines 5 and 10 of claim 6.

In part c) of claim 6, the phrases “the water content” and “the mixture” lack antecedent basis.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller (WO 02/40991, submitted in the Information Disclosure Statement filed on February 8, 2006).

Miller teaches of a calibration standard for the determination of water in a substance using a Karl Fischer reaction. The calibration standard consists of a stable water-containing compound in the form of sodium tartrate dihydrate, and a stable, water-free compound in the form of magnesium stearate. The sodium tartrate dihydrate is stable for an extended duration, without special storage requirements. A process for preparing the calibration standard includes

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sieving crystals of the sodium tartrate dihydrate and magnesium stearate through a #30 mesh screen having 600 micrometer openings, calculating the proper proportions of the sodium tartrate dihydrate and magnesium stearate to produce a certain water content, and then mixing the two components at the calculated ratio using a mixing apparatus to achieve homogeneity. The homogeneous mixture can then be compressed into a tablet form. Miller teaches that it was determined that the combination of sodium tartrate dihydrate with magnesium stearate in the ratio of 95.5:0.5 produced tablets of optimal hardness and with water contents between 0.005-10% by weight, which is the range of water content in prior art, known water calibration standard materials. Tablets formed in this ratio were determined in the Karl Fischer water determination method, and the results obtained were closest to the theoretical water content of the sodium tartrate dihydrate. Miller teaches that a commercial titration apparatus is used for the Karl Fisher determination. See pages 8-11 in Miller.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller (WO 02/40991). For a teaching of Miller, see previous paragraphs in this Office action.

Miller fails to specifically teach that the particle sizes of the water-containing and the water-free components in the calibration standard material are less than 300 micrometers. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to formulate the water-containing sodium tartrate dihydrate and the water-free magnesium stearate in the calibration standard material taught by Miller with particle sizes less than 300 micrometers since particle size is a result effective parameter that can be experimentally adjusted in order to optimize a particular function of the material, such as the water content of the calibration standard.

11. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller in view of Applicants' admitted prior art on pages 1-2 of the specification. For a teaching of Miller, see previous paragraphs in this Office action. Miller fails to teach that the Karl Fischer method of water determination used to test the calibrations standard can be a Karl Fisher oven technique.

Applicants admit on pages 1-2 of the instant specification that determining the water content of a material using a Karl Fischer oven technique is known. In this method, a sample is first heated, and an inert and dry carrier gas flows through a sample space to take up liberated water from the sample and transport it to a titration cell. One known commercial instrument for performing the Karl Fischer oven technique is the Metrohm Sample Processor 774. See pages 1-2 of the instant specification.

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Based upon the combination of Miller and Applicants' admitted prior art in the specification, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the known Karl Fischer oven technique for evaluating the water content of the calibration standard material taught by Miller since Miller discloses that a Karl Fischer titration is used to evaluate the calibration standards, and Applicants teach that Karl Fischer titrations can be performed effectively using an oven technique.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Miller (US 7,122,376 and 7,049,146), Hoffmann et al, Krause, Jackson et al, Dahms and JP 4-297869, who all teach of the use of moisture standard samples in Karl Fischer water determinations.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

September 10, 2007

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
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GROUP 1700